

## REMARKS

### **I. Introduction**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1-26, 27-43, 46-47, and 58-62 are requested to be cancelled. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner. Applicants reserve the right to pursue the subject matter of the canceled claims in subsequent divisional applications.

Claims 44, 48, 50-52, 54-57, 63-64, and 66-67 are currently amended.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier.

Upon entry of this Amendment, claims 44-45, 48-57, and 63-68 will remain pending in the application.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

Applicants note that the Examiner has again rejected arguments for combining Groups I and II of the restriction requirement. See Office Action, page 2, point 4. Applicants believe this decision is inconsistent with MPEP guidelines for applications entering national phase from the PCT and that must be examined according to PCT Rule 13.2, but in order to facilitate examination, Applicants have amended the claims as described below.

Applicants thank the Examiner for the withdrawal of a 35 U.S.C. 112, first paragraph, scope of enablement rejection of claims 44, 45, and 48-62. See Office Action, page 3, point 5.

## **II. Response to Issues Raised by Examiner in Outstanding Office Action**

### **a. Claim Rejections - 35 U.S.C. § 112, Second Paragraph**

Claims 48-50, 54-57, 64-65, and 67-68 are rejected by the Examiner under 35 U.S.C. § 112, second paragraph as being allegedly indefinite. See Office Action, page 3, point 6. The Examiner asserts that the above claims are drawn to non-elected inventions. Applicants have amended the claims and the claims are now drawn to DNA and methods of use. In light of the above amendments, Applicants respectfully request reconsideration and withdrawal of the rejection.

Claim 51 is rejected by the Examiner under 35 U.S.C. § 112, second paragraph as being allegedly indefinite. See Office Action, page 4, point 7. The Examiner asserts that the above claim does not show the deletion of the phrase “of claim 27.” Applicants have amended the claim and respectfully request reconsideration and withdrawal of the rejection.

Claims 44-45, 48-58, and 62 are rejected by the Examiner under 35 U.S.C. § 112, second paragraph as being allegedly indefinite. See Office Action, page 5, point 11. The Examiner asserts, “It is unclear how one identifies a specific *M. tuberculosis* protein by comparison of, e.g. *M. scrofulaceum* with *M. marinum*.” Applicants have amended the claims to remove any language associated with a comparison of any/all virulent *Mycobacterium* to any/all avirulent *Mycobacterium*. In light of the above amendments, Applicants respectfully request reconsideration and withdrawal of the rejection.

### **b. Claim Rejections - 35 U.S.C. § 112, First Paragraph**

Claims 49, 51, 52, and 54 are rejected by the Examiner under 35 U.S.C. § 112, first paragraph for lack of enablement. The Examiner asserts that Prof. Kaufman’s declaration is only persuasive “for nucleic acid sequences which encode whole Rv0068 and Rv3407 as vaccines against one species of *Mycobacterium*, i.e., *M. tuberculosis*.” See Office Action, page 4, point 8. Applicants respectfully request reconsideration and withdrawal of the rejection.

In order to expedite prosecution, and without conceding the merits of the Examiner's rejection, Applicants have amended the claims which are now directed to Rv3407 and Rv0068. Both the specification and the earlier filed declaration of Prof. Kaufman describe in detail the methods for producing vaccines. Data provided by Prof. Kaufman indicate that the specification discloses the methods to enable the production vaccines and show an immune response for both Rv3407 and Rv0068. Applicants thank the examiner for withdrawing all enablement rejections on claims 44 and 45 describing particular proteins, fragments of the proteins, and fusion proteins comprising the disclosed proteins. Using the molecules of claim 44, one can follow the methods described in the specification to produce the vaccines of claims 49, 51, 52, and 54. Those of skill in the art are clearly enabled to produce vaccines against *M. tuberculosis* with Rv3407 and Rv0068. In light of the above arguments, Applicants respectfully request reconsideration and withdrawal of the rejection.

Claims 44, 45, and 48-68 are rejected by the Examiner under 35 U.S.C. § 112, first paragraph. The Examiner alleges that claims directed to proteins that are differentially expressed in virulent strains of *Mycobacterium* compared to avirulent strains of *Mycobacterium* are not enabled. See Office Action pages 4-5, point 9.. Without conceding the merits of the Examiner's rejection, but in order to expedite prosecution, Applicants have removed the comparison language from the claims and now have claims drawn to Rv0068 and Rv3407 from *M. tuberculosis*. In light of these amendments, Applicants respectfully request reconsideration and withdrawal of the rejection.

**CONCLUSION**

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

It is acknowledged that the foregoing amendments are submitted after final rejection. However, because the amendments do not introduce new matter or raise new issues, and because the amendments either place the application in condition for allowance or at least in better condition for appeal, entry thereof by the Examiner is respectfully requested.

Applicants believe the application is in condition for allowance. However, in order to maintain pendency of the application, Applicants are filing a Notice of Appeal.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant(s) hereby petition(s) for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date

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